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10/035,821	10/19/2001	Jane Werling	IDD-5657 CIP2	2470

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EXAMINER

OH, SIMON J

ART UNIT	PAPER NUMBER
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1615

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DATE MAILED: 04/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/035,821

Applicant(s)

WERLING ET AL.

Examiner

Simon J. Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 6) ☐ Other: \_\_\_\_.

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## DETAILED ACTION

### *Double Patenting*

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-29, 65, and 66 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of Claims 98-128 of copending Application No. 10/021,692. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claims 1-29, 65, and 66 in the instant application are word-for-word duplicate claims or substantial duplicate claims corresponding to Claims 98-128 in Application Serial No.

10/021,692.

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Claim 1 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of Claim 119 of copending Application No. 09/953,979. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. Claim 1 in the instant application is a substantial duplicate claims corresponding to Claim 119 in Application Serial No. 09/953,979.

Claims 30-40 are provisionally rejected under the judicially created doctrine of double patenting over Claims 98-126 of co-pending Application No. 10/021,692. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: Independent Claim 30 is considered to be a close variations of Claim 98 in Application No. 10/021,692. Claims 31-40 are further limitations in the instantly claimed method, which substantially correspond to similar limitations found in the claims of Application No. 10/021,692 for similar processes. These similar claim limitations correspond to further modifying the independent base claim, in this case Claim 30, by the addition of energy in various forms to the pre-suspension as a method of controlling particles sizes of the desired compound. Other limitations are drawn to the addition of a seed to the first solution, the second solvent, or the pre-suspension to attain a desired polymorph of a compound. Such claim limitations are substantially similar in structure to those that add further limitations on Claim 98 in co-pending Application No. 10/021,692.

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Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 and 65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The wording of Claim 1, in section (iii), is unclear.

In Claim 65, it is unclear what is meant by the limitations, “essentially free” and “unspecified polymorphic form”.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stainmesse *et al.* (U.S. Patent No. 5,133,908) in view of Cima *et al.* (U.S. Patent Application Publication No. US 2002/0048610)

The Stainmesse *et al.* patent teaches methods of producing nanoparticles comprising first, preparing a liquid phase consisting essentially of a solution of the substance in a solvent or in a mixture of solvents to which may be added one or more surfactants; second, preparing a second liquid phase consisting essentially of a non-solvent or a mixture of non-solvents for the substance and to which may be added one or more surfactants, the non-solvent or the mixture of non-solvents for the substance being miscible in all proportions with the solvent or the mixture of solvents for the substance; third, adding one of the liquid phases prepared in first or second step to the other with moderate stirring so as to produce a colloidal suspension of nanoparticles of the substance; and fourth, if desired, the removal of all or part of the solvent or the mixture of solvents for the substance and of the non-solvent or the mixture of non-solvents for the substance so as to produce a colloidal suspension of nanoparticles of the desired concentration or to produce a powder of nanoparticles (See Abstract; Column 2, Lines 32-52; and Claim 1). Various organic compounds may serve as the substance in the disclosed process, including polymers, waxes, biologically active substances, or pigments (See Column 2, Line 60 to Column 3, Line 38).

The Stainmesse *et al.* patent does not teach the use of seeds in the preparation of particles or of suspensions comprising such particles.

The Cima *et al.* publication discloses various method steps used to produce crystals of a particular substance possessing certain desired characteristics (See Abstract). Various

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components that assist in the disclosed methods are disclosed. The addition of non-solvents to influence the growth of crystals is disclosed (See Sections [0114] and [0115]). The use of various additives, such as surfactants, solvents, seed crystals, impurities, and other excipients is disclosed for the purpose of promoting or controlling nucleation and for influencing various crystal properties, such as crystal habit, polymorphic form, and particle size (See Sections [0014] to [0028], and [0119] to [0132]). The role of adjusting processing parameters for the purpose of influencing the product created by the disclosed methods is also disclosed. Such parameters include temperature, and its influence in altering the state of saturation; time, particularly its role in “ageing”; pH, and its role in determining the physical state and properties of the solid phase; and concentration, particularly the role of supersaturation in influencing the nucleation and growth rate of crystals. Various processing steps are also disclosed, including stirring, filtering, centrifuging, and the input of various types of energy, such as mechanical stimulation, ultrasound, and laser energy (See Sections [0182] to [0185] and [0188] to [0194]). The induction of nucleation by various process steps is disclosed, such as the input of energy, the addition of surfactants, and the alteration of the state of saturation. The induction of precipitation by various process steps is disclosed as well, including the addition of a non-solvent (See Sections [0201] to [0207]). Various analytical methods are also disclosed, including differential scanning calorimetry, or DSC (See Section [0266]). Various pharmaceuticals, suitable for the disclosed methods are also listed, itraconazole among them (See Section [0088], particularly Page 7, 1<sup>st</sup> Column, 4<sup>th</sup> Line).

It would be obvious to one of ordinary skill in the art to combine the teachings of Stainmesse *et al.* and Cima *et al.* into the objects of the instantly claimed invention. One of



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ordinary skill would be motivated to modify the disclosure of Stainmesse *et al.* in view of Cima *et al.* in order to gain greater control of product characteristics, including size and morphology. It is the position of the examiner that one of ordinary skill would be able to use the disclosure of the prior art to create suspensions and particles in accordance with the instantly claimed invention through routine experimentation, with a reasonable expectation of success. Thus, the instantly claimed invention is *prima facie* obvious.

### *Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh  
Examiner  
Art Unit 1615

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April 3, 2003

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